Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Effect of Caffeine on Ileus After Laparotomy

Protocol summary

Study aim
Effect of Caffeine on Ileus After Laparotomy
Design
This study is a randomized controlled clinical trial with no corsair. In this study, which will be conducted in parallel groups, 84 patients who are candidates for laparotomy will be included in the study. Randomization will be done with the help of Randlist software.
Settings and conduct
This study will be performed in Imam Reza Hospital (Tabriz) with the participation of 84 patients. In this study, which was performed without corsaging, 84 patients were randomly divided into two groups; The first group will receive one caffeine tablet every eight hours and the control group will receive one placebo tablet every eight hours.
Participants/Inclusion and exclusion criteria
Inclusion criteria include (1) a candidate for laparotomy, (2) a hospitalized patient, and (3) the ability to take medication and food orally, and exclusion criteria include (1) caffeine sensitivity, (2) and heart rate. Hearts are more than 120 per minute (3) of emergency surgery.
Intervention groups
The intervention group will be given one caffeine tablet every eight hours and the control group will be given one placebo tablet every eight hours.
Main outcome variables
Intestinal movements and sounds

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20140203016473N11**
Registration date: **2020-12-09, 1399/09/19**
Registration timing: **prospective**

Last update: **2020-12-09, 1399/09/19**
Update count: **0**

Registration date
2020-12-09, 1399/09/19

Registrant information
Name
Farzad Kakaei
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1334 1317
Email address
fkakaei@tbzmed.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-01-19, 1399/10/30
Expected recruitment end date
2021-03-20, 1399/12/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Caffeine on Ileus After Laparotomy

Public title
Effect of Caffeine on Ileus After Laparotomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for laparotomy Needs hospitalization Ability to take medicine and food by mouth
Exclusion criteria:
Caffeine sensitivity Heart rate greater than 120 beats per

minute Emergency surgery

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization is performed with Randlist software version 1.2 and participants are divided into two groups of intervention and control.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of medical sciences

Street address
Azadi Ave, Golgasht St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2020-01-20, 1398/10/30

Ethics committee reference number
IR.TBZMED.REC.1398.1140

Health conditions studied

1

Description of health condition studied
Intestinal diseases

ICD-10 code
A07

ICD-10 code description
Other protozoal intestinal diseases

Primary outcomes

1

Description
Intestinal movements and sounds

Timepoint
Three times a day, once every eight hours for three days

Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients applying for laparotomy will receive the intervention the day before surgery. The intervention will be such that they will consume one caffeine tablet every eight hours daily. Bowel sounds and movements will then be monitored for up to three days after surgery.

Category
Treatment - Drugs

2

Description
Control group: Patients applying for laparotomy will receive the intervention the day before surgery. The intervention will be such that they will take one placebo tablet every eight hours daily. Bowel sounds and movements will then be monitored for up to three days after surgery.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Surgery Ward of Imam Reza hospital

Full name of responsible person
Dr Farzad Kakaei

Street address
Golgasht Ave.,Azadi Ave.,Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614695

Phone
+98 41 3334 1317

Email
fkakaei@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Hasan Soleimanpour
Street address
Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.
City
Tabriz
Province
East Azarbaijan
Postal code
5981764686
Phone
+98 41 3336 9696
Email
fkakaei@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
50
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farzad Kakaei
Position
Associate professo
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5981764863
Phone
+98 41 1334 1317
Fax
+98 41 1334 1317
Email
fkakaei@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farzad Kakaei
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5981764863
Phone
+98 41 1334 1317
Fax
+98 41 1334 1317
Email
fkakaei@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farzad Kakaei
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Imam Reza hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5981764863
Phone
+98 41 1334 1317
Fax
+98 41 1334 1317

Email
fkakaei@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available